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(10) # CANADIAN PATENT

(54) ANESTHETIC ARTICLES

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This invention relates to improvement in the administration of anesthetics to body tissue.

One object of the invention is to provide a means for making a patient more comfortable during the treatment of body cavities, openings and passages.

Another object is to provide an improved means for administering anesthetics over prolonged periods, and in correlation with the observable effects of prior dosage.

A particular object of the invention is to provide improved mechanical devices, especially tracheal tube devices and suppositories, which administer surface effective anesthetics over prolonged periods in an improved manner.

According to the invention I have realized that a membrane member can be used to contain a fluid surface-effective anesthetic, and can produce a progressive release at proper rate to tissues of the body in contact with the membrane. By this means extremely prolonged surface anesthesia of tissue can be achieved. Such a membrane device combined with a mechanical device enables use of the latter over a prolonged period without pain.

The invention takes advantage of the impeded diffusion characteristic of membrane material, with the rate of release controlled by the selection of the membrane as well as by the conditions of the fluid itself.

Many materials may be fashioned into such a membrane. Included are "cellophane" (Registered Trade Mark), which incidentally is quite durable and is presently preferred, colloidon, animal membranes such as intestine walls, as well as new membrane materials as they are developed. New materials which presently show promise

include plastic materials rendered semi-permeable by bombardment with particles from nuclear fission and certain silicone materials.

Selection of the membrane depends upon the characteristics of the particular anesthetic fluid. Thus with a water solution anesthetic, which is preferred, "cellophane" is a very good membrane, and the dosage rate can be controlled by thickness; colloidon and animal membranes can also be used.

In the drawings:

Fig. 1 is a side view of one preferred embodiment of the device of the invention;

Fig. 2 is a median section view of a human being illustrating the use of the device of Fig. 1;

Fig. 3 is a view similar t Fig. 2 of another preferred embodiment of the invention;

Fig. 4 is a side view, partially in cross-section, of another preferred embodiment of the invention;

Fig. 5 is a view showing the endotracheal tube of Fig. 4 inserted in the trachea of a patient.

Referring to Fig. 1 a tube 10 of diameter D of flexible membrane material is knotted at both ends 12, 14 defining a bag. A resilient tube 16, of smaller diameter D_1, and of greater stiffness than the walls of tube 10 is disposed within the bag, at one end 14. By ties 18 and 20 the bag is drawn against the tube 16, forming pleats in the bag. Holes 22 and 24 are provided in the tube on either side of the tie 18, enabling the part of the bag hugging the tube to receive liquid from the large end of the bag. The bag is

filled with liquid surface-effective anesthetic 26, the membrane and anesthetic properties cooperatively related to enable anesthetic to be released through the membrane at an effective dosage rate. A bag 28, for instance in the form of a rubber prophylactic article, surrounds this entire assembly, and is tied off, at 30.

In use the large end of the tube 10 serves as a stop, preventing further inward movement of the device. This end also serves as a supply. The resilient bag 28, in the stretched position shown in Fig. 2, serves to maintain pressure upon the bag to assist movement of the anesthetic. It also serves to cover the large end of the membrane bag, preventing loss of anesthetic from that region.

During use the anesthetic need neither be discharged in a short time nor contained completely. Rather, by virtue of the impeded diffusion characteristic of the membrane relative to the anesthetic, a dosage rate can be maintained at a substantially effective level and body tissue in contact with the membrane can be thereby continually anesthetized.

Example 1

A rectal suppository such as shown in Fig. 1 was made and filled with surface-effective anesthetic. For this purpose a 2 inch length of 1 inch diameter "cellophane" tube, having a wall thickness of .002 inch, was knotted at one end at 12, was filled with 20 cc of 2% water base liquid xylocaine* (*Trademark of Astra Pharmaceutical Products, Inc. Worcester, Mass. for lidocaine hydrochloride).

The tube 16 was used for filling, in this instance comprising a rubber tube of 9/16" O.D. and 1/8" wall thickness. It was inserted in the open end of the "cellophane" tube and this open end was tied securely about the rubber tube at 18 and 20.

The "cellophane" tube employed was conventional sterilizing tubing furnished to hospitals by the Edward Weck & Co., division of Sterling Precision Corp. 49-33 31st Place, Long Island City 1, New York. This tubing is regenerated celluose plasticized with glycerol, and lubricated with neutral white oil.

After filling, the "cellophane" tube 10 was tied off at 14, fully enclosing the rubber tube.

The suppository was inserted into the patient following hemorrhoid surgery, in the position shown in Fig. 2. Insertion was facilitated by the relative stiffness of the rubber tube 16.

The patient rested comfortably without need of narcotics for more than six hours before feeling pain. This was the result of administration of the anesthetic by means of the membrane wall of the suppository.

In more recent testing the patient has rested comfortably for more than twelve hours.

The suppository caused no injury to the tissue.

In contrast, with customary procedures the patient feels intense pain and is usually administered 8-10 mg of morphine every three to four hours, for the first 24 hours following surgery.

The effectiveness of the suppository can be prolonged by limiting the membrane area to that contacting the surgical area tissue. This can be accomplished by entirely or partially occluding the remainder of the walls, for instance by making those walls thicker or applying a coating such as rubber, or by means of the bag 28 as shown in Fig. 2. Various controls for the dosage rate of anesthetic are made possible by the device. At first there is the possibility of selection of the kind and concentration of the anesthetic and the membrane material. After a membrane material is selected, e.g. cellophane, then its thickness can be selected. For instance a .004" wall thickness can transmit a lighter, though effective, dose than a wall of .002" thickness. Then, during use, the amount of pressure upon the anesthetic can be adjusted, depending upon observation of the patient, and as well, the temperature of the anesthetic can be adjusted, increase in either increasing the dosage rate.

In addition to the liquid anesthetic, other rectal drugs may be administered through the membrane. For instance to the 20 millimeters of 2% lidocaine hydrochloride of example 1, a concentration of 1 to 100,000 epinephrine can be added. This will promote hemostasis (stop bleeding) and will conserve the anesthetic due to its effect of constricting the blood vessels and thus limiting the rate at which blood carries away the anesthetic.

Referring to Fig. 3 there is shown a rectal suppository in the form of a dumbbell. Preferably each end of the dumbbell is formed of membrane material, filled with surface-effective anesthetic and adapted to administer the anesthetic according to the invention.

The large size of the ends 32 and 34 of the dumbbell serve as stops, preventing inward or outward movement.

Advantageously at least the inner end 34 is formed by a plurality of concentric membrane bags 35, 36, 37, 38. In each space defined between a pair of these bags is held a fraction of the total charge of surface-effective anesthetic. This fraction can be sized so that, in the event of accidental rupture of the outer wall 35, for instance, the sudden release of the amount of surface-effective anesthetic to the body is limited to what the body can easily tolerate. For instance, each of the spaces can be filled with 6 cc of 4% lidocaine hydrochloride.

Furthermore, the plurality of bag walls increase the impedance to travel of anesthetic from the center of the bag, and thus serve to prolong the anesthetic effect of the device and control the dosage rate.

The device is easily formed from a single tube by knotting, filling, knotting the open end, passing the tube over the filled portion, filling the space in between from the other end, knotting at the other end, and so on.

In some cases it is advantageous to fill a central bag, e.g. 38, with water or other neutral agent, and to make that bag wall of impervious material. Thus the over-all size of the device can be increased without increasing the amount of anesthetic being used.

Referring to the embodiment of Figs. 4 and 5 an endotracheal tube 42 is provided having a cuff 40.

The tube 42 can be of conventional design, defining an air passage that extends from the fitting 44 at the exterior end to the interior end. This tube is adapted to be connected to a ventilator to supply air to the lungs of a patient and to exhaust air from the lungs. The tube is formed of resilient material such as heavy rubber.

The cuff 40 is located close to the interior end in the conventional manner. It surrounds the tube 42, defining an annular container, i.e. a short length sheath. It is more flexible than the tube 42. A relatively small supply tube 46 extends from the cuff for inflation purposes.

According to the invention the tissue contacting wall 48 of the cuff 40 is constructed and arranged as a membrane having a diffusion characteristic enabling an effective dosage rate of surface-effective liquid anesthetic 49 to pass through the wall to the tissue of the trachea.

It is possible to fill the supply tube 46 with a syringe. However, referring again to Fig. 5, the inflation of the cuff is better obtained by means of a hydrostatic column 49. This is made possible by virtue of the very flexible material of which the cuff is formed and by making the cuff of a size greater than the trachea. The cuff there-

fore can be distended with substantially no pressure (unlike conventional elastic cuffs), and the needed inflation pressure for creating a seal is determined by the pressure of the respirator. Thus a hydrostatic column of 20 to 30 cm will be adequate to inflate the cuff.

The resultant low force which the cuff exerts against the walls of the trachea, in conjunction with the ability to administer controlled amounts of anesthetic, makes the device suitable for use over very extended periods for polio patients and others requiring such treatment. The pressure can be easily monitored by observing the level of the hydrostatic column.

Example 2

A conventional endotracheal tube was modified by removing the conventional relatively thick walled rubber cuff and affixing a cuff formed of membrane material. In this instance the cuff was formed of the "cellophane" described in example 1, tied at 41 and 43 to the tube 42.

The "cellophane" was folded to hug tightly the outer surface of the endotracheal tube 42, and the tube was inserted through the mouth of the patient. Once in place liquid anesthetic (2% lidocaine hydrochloride) was introduced through supply tube 46 to the cuff 40 causing the cuff to inflate and engage a ring of tracheal tissue 47, thus creating a seal.

While the lungs of the patient were ventilated by means of the tube 42, the anesthetic was progressively applied to the contacting tracheal tissue at an effective dosage due to the impeding diffusion characteristic of the membrane.

This anesthetized the tissue and made the patient much more comfortable than is the normal case, using a conventional tube with only spray-application of anesthetic prior to placing the tube in the trachea.

Use of the endotracheal cuff described permits tolerance of an endotracheal tube by the awake patient. Many times patients weakened by surgery are unable to breath adequately following surgery, and will succumb from asphyxia if not assisted in the act of breathing. Ordinarily the endotracheal tube used during the operation is left in place after the patient returns to consciousness. The endotracheal tube produces violent coughing however, very similar to the reaction a person has when he inhales a peanut into his windpipe. A patient reacting thusly cannot be assisted effectively in the act of breathing. Use of the embodiment of Figs. 4 and 5 however averts this difficulty, for his tracheal tissue will not detect the presence of the tube. One filling with 6-10 cc of 2% lidocaine hydrochloride will last around 10-12 hours.

Among the surface effective anesthetic drugs that are suitable for use are the following: Lidocaine 1-4%, Tetracaine 0.2-0.5%, Dyclonine 0.5-1% Diothane 1%, Hexylcaine 5%, Cocaine 3-5% solution. Lidocaine 2% in volumes of 10-20 c.c. is presently the preferred agent.

Containers formed with walls of diffusion impeding membranes, filled with any of these surface effective anesthetic agents, may be inserted in body openings and in or upon surgical incisions and will provide effective surface anesthesia for 8-12 hours.

What is claims is:

CLAIMS: 814744

1. An applicator device sized and shaped to removably enter a body opening and lie in a body passage, said device including a highly flexible, distensible, thin wall exposed to contact surface tissue that defines the body passage, the wall comprising a generally fluid-tight membrane having a diffusion characteristic for diffusion of surface-effective fluid anesthetic through its thickness, said wall being sealed to form at least a part of an inflatable container adapted to receive surface-effective fluid anesthetic, whereby the yieldable pressure of the fluid anesthetic introduced to said container itself can distend the wall into an intimately conforming tissue-contacting relationship to apply anesthetic to that tissue by diffusion.

2. The device of claim 1 wherein said membrane is selected from the group consisting of "cellophane", colloidon and animal membrane.

3. The device of claim 1 wherein said wall has a thickness of the order of magnitude of .004 inches.

4. The device of claim 1 including a tubular member connected to said membrane and adapted to transmit a second fluid through said passage while the tissue that defines said passage receives anesthetic through said membrane.

5. The device of claim 4 wherein said tube is sized to transmit life-supporting quantities of air into the lungs of a patient, and said membrane forms an inflatable annulus about said tube, whereby said annulus can form a seal between the tube and the tissue of said passage while simultaneously applying surface-effective anesthetic to said tissue.

6. The device of claim 5 wherein said device is an endotracheal tube adapted to be inserted through the mouth, into the trachea of a patient, said tube having an external end adapted for connection to means for introducing air into the patient, said annulus having an outer diameter, when distended, sized to fill the internal diameter of the trachea.

7. The device of claim 1 comprising a suppository sized to be inserted into the anus of a patient and having a membrane wall exposed to engage the tissue of the anus, thereby to anesthetize the painful tissue resulting from a hemorrhoidectomy.

8. The device of claim 7 including an enlarged flexible outer wall member for location outside the anus, to contain the fluid anesthetic, a passage adapted to transmit the anesthetic inwardly to inward wall portions, thereby to supply anesthetic to the painful tissue.

9. The device of claim 8 including an inwardly enlarged member, arranged to position the device.

10. The device according to claim 1, 5 or 6 including a supply tube communicating with said container and adapted to introduce liquid anesthetic to said container when said container has been positioned with respect to the patient, said supply tube including an upwardly extending hydrostatic leg adapted to maintain a predetermined fluid pressure within said container and against said membrane.

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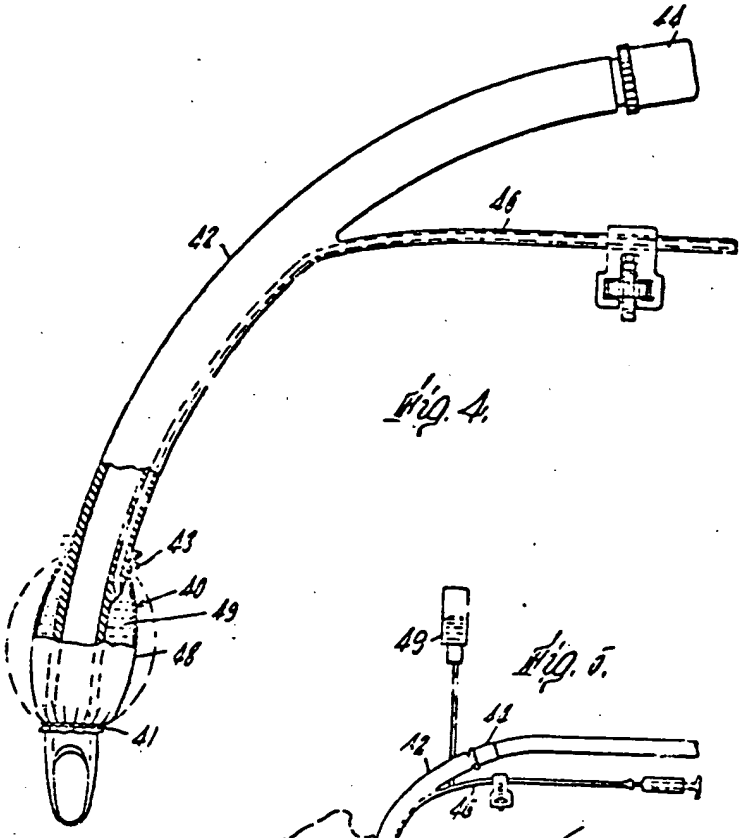

Fig. 4.

Fig. 5.

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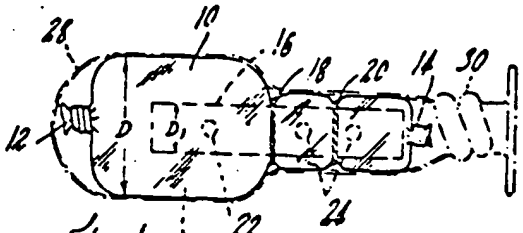

Fig. 1.

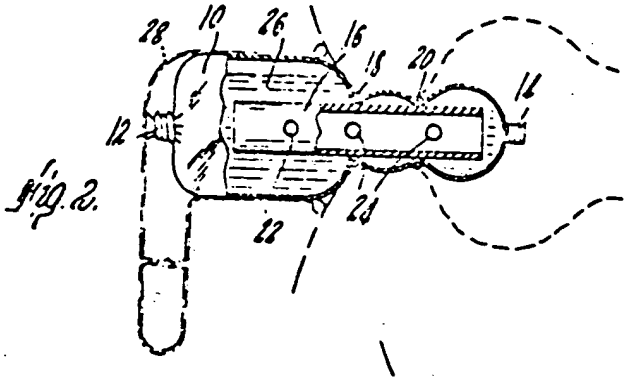

Fig. 2.

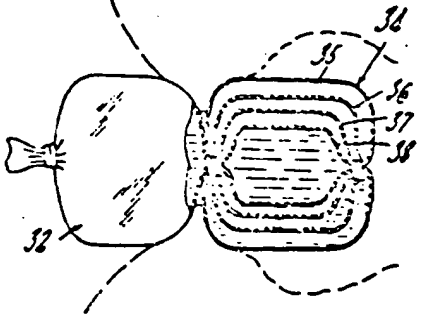

Fig. 3.